

IN THE UNITED STATES DISTRICT COURT FOR THE
MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

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| RUTH SMITH, Individually and as Widow for the |) | |
| Use and Benefit of Herself and the Next Kin of |) | |
| Richard Smith, Deceased, |) | |
| |) | |
| Plaintiff, |) | Civil No. 3:05-0444 |
| |) | Judge Aleta A. Trauger |
| v. |) | (Dist. Of MA No. |
| |) | 1:05-cv-11515PBS) |
| PFIZER, INC., <i>et al.</i> , |) | |
| |) | |
| Defendants. |) | |

**MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS'
MOTION *IN LIMINE* TO EXCLUDE ALL EVIDENCE OF OR REFERENCES
TO WARNER-LAMBERT COMPANY LLC'S GUILTY PLEA OR ANY
RELATED GOVERNMENT INVESTIGATIONS OR AGREEMENTS**

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Pursuant to Federal Rules of Evidence 402, 403, and 404, Defendants Pfizer Inc and Warner-Lambert Company LLC (collectively, “Defendants” or “Pfizer”), respectfully submit this memorandum of law in support of their accompanying motion *in limine* to exclude at trial any and all evidence of or reference by Plaintiff or her counsel before the jury of Warner-Lambert Company LLC’s guilty plea dated May 13, 2004, any negotiation, settlement, or agreement between Pfizer and/or Warner-Lambert and any government entity arising out of the guilty plea, or any related government finding or investigation of the marketing of Neurontin in violation of the Food, Drug, and Cosmetic Act, and the fact of any such investigation (collectively, the “Plea”).

PRELIMINARY STATEMENT

Plaintiff seeks to put before the jury a guilty plea and related documents and evidence that have no relevance whatsoever to the issues to be decided in this products liability case. The Plea relates to specific violations of pharmaceutical marketing law that took place over ten years ago and several years before Decedent, Richard Smith, was first prescribed Neurontin in 2004. None of the conduct at issue in the Plea remotely involved or reached Mr. Smith or his prescribing healthcare providers. In fact, the Plea has nothing to do with *any* of the questions for the jury to decide in this case: whether Neurontin causes suicidal behavior; whether, at the time Neurontin was prescribed to Mr. Smith, Neurontin’s label contained adequate warnings; whether Mr. Smith was taking Neurontin at the time of his death; and whether Mr. Smith’s decision to take his own life resulted from his alleged use of Neurontin or from his many other well-accepted suicide risk factors. The only conceivable reason Plaintiff would seek to place the Plea before the jury is to invite the jury to decide the case based not on the facts and the law at issue, but instead on a visceral reaction to the unrelated conduct by Warner-Lambert that is the subject of the Plea.

The Supreme Court has made clear that liability cannot be imposed based upon conduct that did not cause harm to the plaintiff. To punish a defendant based upon harm to persons “not

before the court . . . would amount to a taking of ‘property’ from the defendant without due process.” *Philip Morris USA v. Williams*, 549 U.S. 346, 349 (2007). The Supreme Court has made clear that courts should not countenance desultory attempts to find a relevance hook that only obscures the real – and impermissible – purpose for which such evidence is offered: to induce the jury to punish a defendant for conduct that is not before them.

Evidence related to the Plea and the underlying government investigation is inadmissible for several reasons. First, the Plea is wholly irrelevant to the claims in this case and should be excluded on that ground alone under Rules 401 and 402 of the Federal Rules of Evidence. Second, because the Plea is irrelevant and could lead the jury to impose compensatory and punitive liability for unrelated conduct, introduction of the Plea would violate Pfizer’s due process rights. Third, the unfair prejudice and undue delay that evidence of or references to the Plea would inevitably generate far outweigh its non-existent probative value and require its exclusion under Rule 403. Fourth, given the lack of relevance of the Plea to Plaintiff’s claims, the only plausible reason that Plaintiff might have for introducing it would be as improper character evidence to attempt to establish that Pfizer is a “bad actor.” Rule 404(b) flatly prohibits this. Finally, the Plea is not admissible as impeachment evidence.

Accordingly, as set forth in greater detail below, the Court should preclude Plaintiff from introducing or otherwise referencing the Plea before the jury.

THE PLEA

In May 2004, Warner-Lambert pleaded guilty to two strict-liability, misdemeanor violations under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-399a (the “FDCA”), related to its marketing of Neurontin between April 1995 and August 1996. (*See* Ex. A, Plea and Information.)¹ Off-label marketing, outside of certain safe harbors created by the Food and Drug Administration (“FDA”), constitutes a violation of the FDCA, regardless of

¹ All exhibits are attached to the accompanying Declaration of Mark S. Cheffo.

(1) the efficacy of the drug, (2) the safety of the drug,² or (3) the truth or falsity of any statements made by the manufacturer to the physician.³ Accordingly, the Plea is not evidence that Warner-Lambert acted fraudulently or intentionally, or that Neurontin is not efficacious. Indeed, in its summary of the elements of the counts, the court that accepted the Plea specifically noted that scienter was not an element. (Ex. B, Tr. of 6/7/04 Waiver, Change of Plea and Sentencing Hearing (“Plea Transcript”) at 10:4-9.)⁴

In the course of the Plea hearing, Warner-Lambert acknowledged that the facts set forth in the Information dated May 13, 2004 were factually accurate. Significantly, the Information outlined and described *specific instances* in 1995 and 1996 in which Warner-Lambert’s marketing activities violated the relevant provisions of the FDCA. For example, the Information identifies a particular “teleconference . . . in which [a] Medical Director promoted off-label uses of Neurontin to the doctors participating in the teleconference.” (Ex. A, Information ¶ 36.) Because the Information is limited to the specific instances set forth therein, Warner-Lambert’s acknowledgment of the truth of the facts contained in the Information is equally limited to those specific instances. Warner-Lambert denied, and Pfizer continues to deny, the existence of any intentional nationwide scheme to promote Neurontin for off-label use, a fact that is consistent with the scope of the guilty Plea and accompanying Information. Finally, neither the guilty Plea nor the Information addressed issues related to Neurontin’s efficacy.

² See *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 350 (2001) (“[T]he ‘FDA itself recogniz[es] the value and propriety of off-label use’” (citation omitted)).

³ See *In re Neurontin Mktg. & Sale Practices Litig.*, 244 F.R.D. 89, 92 & n.6 (D. Mass. 2007) (“*In re Neurontin I*”); *In re Neurontin Mktg., Sales Practices & Prods. Liab. Litig.*, 257 F.R.D. 315, 329 (D. Mass. 2009) (“*In re Neurontin III*”).

⁴ Although the specific violations to which Warner-Lambert pleaded guilty were misdemeanors, the conduct was elevated to felony status because of a previous agreement between Warner-Lambert and the government in an unrelated matter years earlier. (Plea Transcript at 6:22-7:15.) There is no conceivable relevance to the amount paid as a fine by Warner-Lambert, and Plaintiff should not be allowed to disclose that amount to the jury.

ARGUMENT

I. THE PLEA IS IRRELEVANT TO PLAINTIFF'S CLAIMS

The Plea is irrelevant to the current dispute and, therefore, inadmissible.⁵ Evidence is relevant only if it makes the existence of a fact of consequence to the determination of an action more or less probable. *See* Fed. R. Evid. 401; *see also* 2 Jack B. Weinstein & Margaret A. Berger, *Weinstein's Federal Evidence* § 401.04[2][a] (Joseph M. McLaughlin ed., 2d ed. 2007) (“Relevance is not inherent in any item of evidence but exists only as a relation between an item of evidence and a matter properly provable in the case.”). “Evidence which is not relevant is not admissible.” Fed. R. Evid. 402; *see also United States v. Vasilakos*, 508 F.3d 401, 409 (6th Cir. 2007). It is also well settled that, “[w]hether or not a fact is of consequence” to the determination of an action “is determined not by the Rules of Evidence but by substantive law.” 1 Jack B. Weinstein & Margaret A. Berger, *Weinstein's Federal Evidence* § 401[03], at 401-19 (Joseph M. McLaughlin ed., 2d ed. 1988); *see also Sherrod v. Berry*, 856 F.2d 802, 804 (7th Cir. 1988). The substantive law at issue here is Tennessee law governing failure-to-warn and fraud by omission claims in product liability actions like this one.

A. The Plea Is Irrelevant To Plaintiff's Failure-To-Warn Claim

The Plea is not relevant to Plaintiff's products liability claims under Tennessee law,

⁵ Even if this Court were to find the plea admissible under Tennessee law, it must be limited to the plea itself, because only the plea can be considered a party admission or a judicial determination. *See* Fed. R. Evid. 801(d)(2), 803(22). All other associated documents – including the Sentencing Memorandum, Information, and government press releases – are inadmissible as hearsay without an exception. Indeed, the Sentencing Memorandum submitted by the government at the time of the Plea agreement is nothing more than a series of allegations by the government regarding conduct that Warner-Lambert never admitted to having engaged in. *See, e.g., Kushner v. Beverly Enters., Inc.*, 317 F.3d 820, 829-30 (8th Cir. 2003) (refusing to consider, on a motion to dismiss, in a civil case, a sentencing memorandum prepared by the government in a previous criminal action against a subsidiary of defendant because “[t]he government’s sentencing memorandum is a position paper offered here by the [plaintiffs] for the truth of the matters asserted therein, which the defendants dispute”). Moreover, this Court’s ruling regarding the plea should not extend to civil settlements or amounts paid for civil settlements, as such evidence is inadmissible under Rule 408. *See Cappello v. Duncan Aircraft Sales of Fla., Inc.*, 79 F.3d 1465, 1476 (6th Cir. 1996) (finding that evidence of settlements with other passengers in an airplane crash was inadmissible under both Rule 408 and Tennessee civil procedure).

which raise the following issues for the jury: (1) whether Neurontin is capable of causing suicidal behavior (general causation) and whether Pfizer knew or should have known of this alleged risk; (2) whether Mr. Smith was taking Neurontin at the time of his death (specific causation); (3) whether Mr. Smith's suicide resulted from Neurontin, as opposed to the many suicide risk factors from which he suffered (specific causation); and (4) whether an alleged inadequate warning in Neurontin's labeling proximately caused Mr. Smith's suicide (legal causation). *See, e.g., Pride v. Bic Corp.*, 54 F. Supp. 2d 757, 763 (E.D. Tenn. 1998), (stating that an "essential element of any products liability action in Tennessee is that the defect in question proximately caused the plaintiff's injury"), *aff'd*, 218 F.3d 566 (6th Cir. 2000); *Harden v. Danek Med., Inc.*, 985 S.W.2d 449, 451 (Tenn. Ct. App. 1999) ("In order to recover for failure to warn under the learned intermediary doctrine, a plaintiff must show: (1) that the defendant failed to warn the physician of a risk associated with the use of the product not otherwise known to the physician; and (2) that the failure to warn the physician was both a cause in fact and proximate cause of the plaintiff's injury."); *see also In re Neurontin Mktg., Sales Practices & Prods. Liab. Litig.*, 612 F. Supp. 2d 116, 123 (D. Mass. 2009) ("*In re Neurontin II*") ("In order to prevail in a pharmaceutical personal injury case, a plaintiff must establish two types of causation: general and specific."). The Plea is completely irrelevant to each of these substantive inquiries.

It is indisputable that the Plea does not address issues regarding Neurontin's safety, much less whether it is capable of causing suicide, whether Defendants had such knowledge, whether its labeling contained adequate warnings on suicide, whether Mr. Smith was taking Neurontin at the time of his death, or what caused Mr. Smith to take his own life. Rather, as described above, the Plea involves a limited number of strict-liability violations relating to the *marketing* of Neurontin. Furthermore, Plaintiff has not established any causal connection between Mr. Smith or his prescribing healthcare providers and any of the events described in the Plea. This is unsurprising, considering that the events relevant to the Plea took place in 1995 and 1996, more than seven years before Mr. Smith received his first prescription for Neurontin in March 2004.

B. The Plea Is Irrelevant To Plaintiff's Fraudulent Concealment Claim

The Plea is similarly irrelevant to Plaintiff's fraudulent concealment claim, which is the only aspect of Plaintiff's fraud claim remaining. The MDL court granted Defendants' "motion to dismiss all fraud claims alleging affirmative misrepresentations or a suppression of information as part of a national marketing campaign because there is no allegation of reliance on specific statements or misrepresentations." *See In re Neurontin Mktg., Sales Practices & Prods. Liab. Litig.*, 618 F. Supp. 2d 96, 112 (D. Mass. 2009) ("*In re Neurontin IV*"). As to the instant lawsuit, it granted the motion and dismissed all fraud claims based on alleged affirmative misrepresentations. *Id.* at 114. While the MDL court denied the motion as to claims of misrepresentation by concealment, it provided that even concealment claims were dismissed "to the extent they are premised on the claim of fraudulent omissions in the national advertising and marketing campaign." *Id.* As a result, evidence related to national advertising, marketing, and promotion (whether for off-label use or otherwise), including the Plea, is not relevant to any issue in this lawsuit.⁶

The MDL court has also recognized that off-label promotion – the subject of the Plea – does not constitute fraud, much less the narrow fraud by omission claim that was allowed to proceed. *See, e.g., In re Neurontin III*, 257 F.R.D. 315, 329 (D. Mass. 2009) (denying class certification and holding that consumer plaintiffs must establish that "defendants' *fraudulent* marketing, not simply their off-label marketing, caused the prescriptions written for the putative class members"); *see also In re Neurontin I*, 244 F.R.D. 89, 92 n.6 (D. Mass. 2007) ("While off-label marketing is illegal, there is no private right of action to enforce it. To succeed on their claims, plaintiffs must prove that defendants' representations were false, along with all other elements of their claims." (citation omitted)). Just as Plaintiff may not rely on generalized evidence of off-label or fraudulent marketing to satisfy her burden to prove fraud, she should not be permitted to use the Plea as a proxy for evidence of fraud that does not exist in this case.

⁶ Defendants have separately moved *in limine* to exclude evidence of Defendants' marketing and promotional activities. Defendants incorporate that motion herein by reference.

As the MDL court found, there is no evidence that Defendants made any affirmative misrepresentation of material fact regarding Neurontin to Mr. Smith's prescribing healthcare providers, much less that they were the target of, or relied on, any statement at issue in the Plea. *In re Neurontin IV*, 618 F. Supp. 2d at 112. Moreover, as established above, nothing in the Plea is relevant to Neurontin's safety or any alleged intentional concealment of material information about its side effects, the only remaining basis for Plaintiff's fraud claim. *See id.* at 113-14. Accordingly, the Plea should be excluded as irrelevant to Plaintiff's fraud claim.

II. INTRODUCTION OF THE CRIMINAL PLEA IS IRRECONCILABLE WITH THE SUPREME COURT'S DECISIONS IN *CAMPBELL* AND *PHILIP MORRIS* AND WILL RESULT IN A VIOLATION OF DEFENDANTS' DUE PROCESS RIGHTS

Recent decisions of the Supreme Court make plain that it would be improper and a denial of Pfizer's due process rights for the jury to impose punitive damages based upon the conduct that was the subject of the Plea. In *Philip Morris USA v. Williams*, 549 U.S. 346 (2007), the Supreme Court held, unequivocally, that punitive damages can be imposed only for conduct that *caused harm to the plaintiff*. As the Court stated: "[T]he Constitution's Due Process Clause forbids a State to use a punitive damages award to punish a defendant for injury that it inflicts upon nonparties or those whom they directly represent, *i.e.*, injury that it inflicts upon those who are, essentially, strangers to the litigation." *Id.* at 353; *see also State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 424 (2003) ("The reprehensibility guidepost does not permit courts to expand the scope of the case so that a defendant may be punished for any malfeasance, which in this case extended for a 20-year period."). By extension, if the Plea cannot support *punitive* damages, the jury certainly cannot award compensatory damages based upon such conduct.

Thus, Plaintiff should not be allowed to manufacture "relevance" arguments for evidence of the Plea by arguing that such evidence is relevant to the issue of punitive damages. The Supreme Court in *Campbell* made clear that, as a matter of due process, dissimilar conduct has no place in the analysis of a defendant's reprehensibility for purposes of punitive damages and should be excluded as irrelevant. *See* 538 U.S. at 422-23. Under the Supreme Court's

punitive damages jurisprudence, only evidence of conduct that is similar to the conduct that resulted in harm to the plaintiff may have any relevance to establishing the reprehensibility of a defendant's conduct toward the plaintiff. *See id.* at 423-24. Dissimilar conduct cannot be used to show repeated misconduct or "recidivism" on the part of a defendant. As the Supreme Court stated in *Campbell*, if punitive damages are to be justified on the grounds that the defendant is a "recidivist," due process requires courts to "ensure the conduct in question *replicates* the prior transgressions." *Id.* at 423 (emphasis added).

Moreover, all of the Supreme Court's concerns about the imposition of punitive damages based upon conduct that did not cause harm to Plaintiff apply with even greater force to Plaintiff's claims for compensatory damages. Indeed, it is hornbook law that compensatory damages must be based upon the harm caused to the plaintiff and not others. *See, e.g., Bach v. First Union Nat'l Bank*, 486 F.3d 150, 153 (6th Cir. 2007) (observing that compensatory damages are designed to compensate the actual harm suffered by a particular plaintiff); *Saldana Sanchez v. Vega Sosa*, 175 F.3d 35, 36 (1st Cir. 1999) (affirming a jury instruction stating that "[t]he purpose of compensatory damages is to make the plaintiff whole – that is, to compensate the plaintiff for the damage that the plaintiff has suffered"). Plaintiff may argue that the off-label marketing at issue in the Plea is relevant to prove compensatory damages for her fraud claims. But, as the MDL Court recognized, off-label marketing, even if it occurred, is not itself fraudulent, *see In re Neurontin I*, 244 F.R.D. at 92 n.6, and, in any event, Plaintiff has not established any causal connection between Mr. Smith or his prescribing healthcare providers and any of the events encompassed within the Plea, as defined above.⁷ Due process precludes the

⁷ Nor may Plaintiff attempt to draw a causal connection through a "fraud on the market" theory, which has never been recognized outside the securities fraud context. *See In re Neurontin IV*, 618 F. Supp. 2d 96, 111 (D. Mass. 2009) (observing that "no court has ever adopted a 'fraud on the market' type theory outside the securities fraud context, and the majority of courts which have had occasion to extend the theory to common law fraud cases have expressly declined to do so." (citation omitted)). Thus, Plaintiff can only recover in this action to the extent she can show that Mr. Smith was prescribed Neurontin due to reliance on misrepresentations received by him or his prescribing healthcare providers and that such Neurontin prescriptions proximately caused his suicide. Plaintiff cannot recover based upon representations allegedly made to the community or market at large.

imposition of compensatory damages based on such unrelated conduct.

In *Campbell*, the Supreme Court held unconstitutional the Utah courts' punishment of twenty years of various dissimilar conduct by the defendant, explaining that courts are not permitted "to expand the scope of the case so that a defendant may be punished for any malfeasance." 538 U.S. at 424. Punishment based on dissimilar conduct "creates the possibility of multiple punitive damages awards for the same conduct," since "nonparties are not bound by the judgment some other plaintiff obtains." *Id.* at 422-23. A punitive damages award based on conduct unrelated to the plaintiff's harm enters the "zone of arbitrariness" that violates due process. See *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 568 (1996). To allow Plaintiff to introduce evidence of the Plea on the issue of "reprehensibility" does not satisfy *Campbell*'s requirement that the conduct replicate the conduct directed at the plaintiff. See *IGEN Int'l, Inc. v. Roche Diagnostics GmbH*, 335 F.3d 303, 313-14 (4th Cir. 2003) (holding that evidence that the defendant engaged in a scheme to put the plaintiff out of business could not support a punitive damage award under *Campbell*, when the conduct alleged was independent of the acts upon which liability was based); *Stroud v. Abington Mem'l Hosp.*, 546 F. Supp. 2d 238, 258-59 (E.D. Pa. 2008) (finding that allegations of a cover-up, which were independent of the basis for imposing liability on the defendant, could not support punitive damages); *Estate of Embry v. GEO Transp. of Ind., Inc.*, 478 F. Supp. 2d 914, 922-23 (E.D. Ky. 2007) (excluding evidence of dissimilar out-of-state conduct because it lacked any proximate relationship with the in-state harm and thus served "no deterrent purpose"); *Richardson v. Tricom Pictures & Prods., Inc.*, 334 F. Supp. 2d 1303, 1324 (S.D. Fla. 2004) (applying *Campbell* and holding that prior allegations of sexual harassment made against company employee involved dissimilar conduct and were irrelevant to determination of a punitive damages award against company), *aff'd*, 183 F. App'x 872 (11th Cir. 2006).

Further, in *Philip Morris*, the Court explained that to allow punitive damages to be based upon harm to non-parties would violate due process by denying the defendant "'an opportunity to present every available defense.'" *Philip Morris*, 549 U.S. at 353 (quoting *Lindsey v. Normet*,

405 U.S. 56, 66 (1972)). The Supreme Court explained that “to permit punishment for injuring a nonparty victim would add a near standardless dimension to the punitive damages equation,” magnifying the due process “risks of arbitrariness, uncertainty and lack of notice.” *Philip Morris*, 549 U.S. at 354; *see also Gore*, 517 U.S. at 568 (observing that a punitive damages award based on conduct unrelated to the plaintiff’s harm enters the “zone of arbitrariness” that violates due process).

The Plea is also objectionable because it involves conduct in other states. The introduction of such evidence would also contravene the holding in *Campbell* that, as a matter of due process, state sovereignty and comity, punitive damages may not be based on a defendant’s conduct in other states. *See* 538 U.S. at 422. The Court explained that “[a] basic principle of federalism is that each State may make its own reasoned judgment about what conduct is permitted or proscribed within its borders, and each State alone can determine what measure of punishment, if any, to impose on a defendant who acts within its jurisdiction.” *Id.* Therefore, the Court concluded both that a jury “may not use evidence of out-of-state conduct to punish a defendant for action that was lawful in the jurisdiction where it occurred” and that a State has no “legitimate concern in imposing punitive damages to punish a defendant for *unlawful* acts committed outside of the State’s jurisdiction.” *Id.* at 421-22 (emphasis added). Punishment that serves no legitimate State interest and adjudication of conduct occurring outside the State and affecting persons not before the court offend due process. *Id.*⁸ Consequently, as a matter of constitutional due process, evidence of unrelated cases involving Pfizer in other states may not be considered for purposes of punitive damages and should be excluded.

⁸ In *White v. Ford Motor Co.*, 312 F.3d 998 (9th Cir. 2002), the Ninth Circuit explained the federalism concerns that prohibit punishment even of unlawful out-of-state conduct. *See id.* at 1014, 1017-18. Because “the difference in how [states] penalize . . . tortious conduct expresses significantly different policy choices,” the federalism concerns of *BMW* apply with equal force to the punishment and deterrence of unlawful out-of-state conduct. *Id.* at 1018. Thus, “‘a State may not impose economic sanctions on violators of its laws with the intent of changing the tortfeasors’ . . . conduct in other States,’ whether the extraterritorial conduct is lawful or not.” *Id.* (alteration in original, footnote omitted, quoting *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 572 (1996)).

All of the concerns expressed by the Supreme Court in *Philip Morris* and *Campbell* are present here. First, there is the very real risk that the jury will impose liability based upon conduct for which Defendants have already been punished. Second, allowing liability to be imposed based upon conduct that did not cause harm to Plaintiff is too standardless and arbitrary to comport with due process. Finally, requiring a defendant to defend against not only the plaintiff's case, but causally unconnected conduct stretching over a lengthy period of years imposes an impossible burden on a defendant, effectively depriving it of an opportunity to present a full and complete defense. This is especially true in this case where the Court has limited each side to a certain number of hours to present evidence.

Moreover, it is a longstanding tenet of the law that a jury may not impose liability based upon the perceived character of the defendant or based upon a belief that a defendant had a propensity to act a certain way. Thus, the Federal Rules exclude character and propensity evidence. *See infra* Section II. Again, the Supreme Court has explained that this issue transcends concerns of relevance and prejudice; it implicates fundamental due process rights of a defendant:

A defendant should be punished for the conduct that harmed the plaintiff, not for being an unsavory individual or business. Due process does not permit courts, in the calculation of punitive damages, to adjudicate the merits of other parties' hypothetical claims against a defendant under the guise of the reprehensibility analysis

Campbell, 538 U.S. at 423.

The due process concerns are magnified here where the evidence sought to be excluded is a criminal plea. The enormous potential for prejudice in these circumstances has been well-recognized. *See, e.g., Int'l Shoe Mach. Corp. v. United Shoe Mach. Corp.*, 315 F.2d 449, 459 (1st Cir. 1963) (“[E]vidence of a judicial determination of prior illegal conduct on the part of the defendant cannot help but have a great emotive impact on a jury. ‘The deep tendency of human nature to punish, not because our victim is guilty this time, but because he is a bad man and may as well be condemned now that he is caught is a tendency which cannot fail to operate with any jury, in or [out] of court.’” (quoting 1 Wigmore, Evidence, § 57 (3d ed. 1940))). Where, as here,

the jury is unlikely to understand the limited scope of the Plea, the risk is even greater.

III. THE PLEA IS UNFAIRLY PREJUDICIAL

Even if Plaintiff is able to conjure some relevance for the Plea, such as on the issue of intent, it remains inadmissible as unfairly prejudicial under Federal Rule of Evidence 403. Courts, including the Supreme Court, have rejected attempts to justify introduction of prejudicial evidence of alleged conduct that did not cause harm to a plaintiff on the grounds that it was evidence of intent. For example, in *Campbell*, the Supreme Court rejected the plaintiffs' argument that the evidence at issue went to motive. *See* 538 U.S. at 422. The plaintiffs argued that the evidence was probative of a general scheme to reduce the amount of money paid to claimants, both as a result of first-party and third-party claims. *See id.* at 423-24. Observing that liability should have been imposed only for the conduct that harmed the plaintiffs, the Supreme Court held that the trial court committed error when it allowed the plaintiffs to use the case "as a platform to expose, and punish, the perceived deficiencies of State Farm's operations throughout the country." *Id.* at 420.

As the Supreme Court explained in *Philip Morris*, given the risk of unfairness, it is the trial court's responsibility to make sure that the jury answers "the right question, not the wrong one." *Philip Morris*, 549 U.S. at 355. Here, the jury will be asked to decide: whether Neurontin can cause suicide; whether Neurontin's label contained adequate warnings in 2004; whether Mr. Smith was taking Neurontin at the time of his death; and whether Mr. Smith's decision to take his own life resulted from his alleged use of Neurontin. The Plea will not help the jury answer those questions. Instead, Plaintiff hopes that the jury will be confused by such evidence so that it answers the wrong question. The only way to make sure that the jury answers the right question is to exclude the evidence. *See, e.g., United States v. Solorio-Soto*, 300 F. App'x 487, 488 (9th Cir. 2008) (holding that limiting instruction that prior bad acts evidence of similar crimes could only be used to show whether charged offense was committed "knowingly" was insufficient to cure prejudice).

Even if the Plea has some tangential relevance to the issues in this lawsuit, any probative

value would be outweighed by the risk of unfair prejudice or juror confusion. Accordingly, the Plea should be excluded pursuant to Rule 403. *See, e.g., Schrand v. Fed. Pac. Elec. Co.*, 851 F.2d 152, 156 (6th Cir. 1988) (noting that evidence should be excluded under Rule 403 where it has a tendency “to confuse the issue by focusing the jury’s attention on . . . totally unrelated events”). The introduction of evidence that Warner-Lambert pleaded guilty to violations of the FDCA in the marketing of Neurontin – notwithstanding the irrelevance of those violations to the facts and claims in the instant dispute – would almost certainly increase the likelihood that a jury in this case would reach a decision based not on the facts properly before them, but on the basis of the guilty plea.

Indeed, courts have cautioned that the danger of unfair prejudice is especially severe in the case of “evidence of a judicial determination of prior illegal conduct on the part of the defendant,” because “[t]he deep tendency of human nature to punish, not because our victim is guilty this time, but because he is a bad man and may as well be condemned now that he is caught is a tendency which cannot fail to operate with any jury.” *Int’l Shoe*, 315 F.2d at 459 (citation omitted) (affirming, in civil antitrust action, trial court’s exclusion of antitrust decree, findings, and opinion in prior government case); *see also Coleman Motor Co. v. Chrysler Corp.*, 525 F.2d 1338, 1351 (3d Cir. 1975) (“A jury is likely to give a prior verdict against the same defendant more weight than it warrants.”); *United States Football League v. NFL*, 634 F. Supp. 1155, 1173 (S.D.N.Y. 1986) (holding that introduction of prior judgments “would permit plaintiffs to create an ‘aura of guilt’ or to ‘imply new wrongdoing from past wrongdoing’”) (citations omitted); *Williams v. Drake*, 146 F.3d 44, 48-49 (1st Cir. 1998) (affirming, in related civil suit, the exclusion of a guilty plea previously entered by plaintiff before a prison disciplinary board).

IV. THE PLEA IS IMPROPER CHARACTER PROPENSITY EVIDENCE

The Plea should also be excluded under Federal Rule of Evidence 404(b) as improper character propensity evidence. The Sixth Circuit has held that a proponent of prior bad acts evidence must establish four requirements:

(1) the evidence must be directed toward establishing something other than a party's propensity to commit the act charged; (2) the other act must be similar enough and close enough in time to be relevant to the matter at issue; (3) the evidence must be such that the jury could find that the act occurred and that the party in question committed it; and (4) the prejudicial effect of the evidence must not clearly outweigh its probative value.

McLeod v. Parsons Corp., 73 F. App'x 846, 854 (6th Cir. 2003) (citation omitted). As demonstrated above, the Plea is irrelevant to this dispute and will cause unfair prejudice. Because the Plea is not relevant to Plaintiff's claims, the only possible use of the Plea is to show a propensity for improper conduct, which is specifically precluded by Rule 404(b). *Id.*

Plaintiff may try to fit the Plea within one of Rule 404(b)'s exceptions, most likely intent. However, courts have made clear that the exceptions must be narrowly construed so that the prohibition against character evidence is not reduced to a hollow pronouncement. For example, courts have repeatedly held that Rule 404(b) does not permit evidence of prior alleged bad acts in order to show *generalized intent* to commit the act at issue in the litigation. *See, e.g., Fisher v. Am. Gen. Fin. Co.*, 52 F. App'x 601, 606-07 & n.3 (4th Cir. 2002) (per curiam) (evidence that defendant's employees routinely fabricated personal property descriptions on loan applications was relevant only of a generalized intent to commit dishonest acts and, therefore, inadmissible under Federal Rule of Evidence 404(b)); *Crawford v. Yellow Cab Co.*, 572 F. Supp. 1205, 1208-09 (N.D. Ill. 1983) (rejecting argument that evidence of other bad acts was admissible to prove that the defendant's actions were "consistent with its corporate practice and policy of indifference to the duty to safely entrust vehicles"). Likewise, courts have held that a profit motive is too generalized an intent to justify the introduction of evidence of other conduct. *See, e.g., Jenkins v. TDC Mgmt. Corp.*, 21 F.3d 436, 440-41 (D.C. Cir. 1994) (holding that prior conduct evidence proffered to demonstrate, *inter alia*, "greed," inadmissible under Federal Rule of Evidence 404(b) because it was "only a shade less general than a claim that [the defendant] was a bad man").

As the Third Circuit has explained, "'a proponent's incantation of the proper uses of [Rule 404(b) evidence] . . . does not magically transform inadmissible evidence into admissible

evidence.’” *Becker v. ARCO Chem. Co.*, 207 F.3d 176, 191 (3d Cir. 2000) (citation omitted) (alteration in original). Rather, the relevance of the evidence must be established by linking logical inferences to the specific facts at issue in the lawsuit. *See McLeod*, 73 F. App’x at 854 (excluding evidence under Rule 404(b) because proponent failed to show a “clear nexus between” the evidence and the facts of the case). At no point can one of the links be that the defendant had the propensity to act a certain way. *See Becker*, 207 F.3d at 191. Here, the evidence is not proffered to show a causal nexus to Plaintiff’s claimed injury. The evidence is offered only to show propensity, which Rule 404 (as well as the Supreme Court’s decision in *Campbell*) does not allow.

V. THE PLEA IS NOT ADMISSIBLE AS IMPEACHMENT EVIDENCE

The Plea is also inadmissible as impeachment evidence. First, Federal Rule of Evidence 609 authorizes the use of a witness’ prior conviction only to attack the individual witness’ credibility. “[I]t is axiomatic that *it is only the testifying witness’ own prior convictions* that should be admissible on cross-examination to impeach his credibility.” *Walden v. Georgia-Pacific Corp.*, 126 F.3d 506, 523 (3d Cir. 1997) (emphasis added). Thus, “Rule 609 does not permit corporate convictions to be used to impeach the credibility of employee witnesses who were not directly connected to the underlying criminal act.” *Id.* at 524. As the Third Circuit explained in *Walden*:

Criminal acts are relevant to a witness’ credibility only if that witness actually participated in the criminal conduct. It strains logic to argue that an employee’s credibility is properly brought into question by the mere fact that he or she is presently employed by a corporation that in some unrelated manner was guilty of dishonest acts, no matter how egregious

Id. at 523-24.

Second, as discussed above, the Plea was limited to certain strict liability violations of the FDCA’s labeling and promotional provisions. The Plea is not relevant to impeach by contradiction in the absence of witness testimony inconsistent with the specific admissions contained in the Plea. *See Fed. R. Evid.* 613. Thus, Plaintiff would first have to elicit testimony on an irrelevant subject, obtain inconsistent testimony, and then offer the Plea as impeachment.

The relevancy requirements may not be circumvented so easily.

Moreover, because the Plea did not involve a crime of dishonesty or false statement, such as perjury, it cannot be offered under Rule 609 to show the alleged propensity of a witness to testify truthfully. *See* Fed. R. Evid. 609(a)(2); *see also United States v. Scisney*, 885 F.2d 325, 326 (6th Cir. 1989) (holding that simply because a crime involves “moral turpitude” does not establish that it involves “dishonesty or false statements” as required by Rule 609(a)(2)).

CONCLUSION

For the reasons set forth above, Defendants respectfully request that the Court grant their motion *in limine* to exclude any evidence of or reference to the Plea at trial.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this the 16th day of April 2010, I electronically filed the foregoing document with the Clerk of the Court, United States District Court for the Middle District of Tennessee, using the CM/ECF system. True and correct copies of the foregoing documents are being served via the Court's CM/ECF system on the following:

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